



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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WARNING LETTER

MAR 31 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

**VIA FEDERAL EXPRESS AND
FACSIMILE**

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David Mercer
Chief Executive Officer
Interpore Cross International
181 Technology Drive
Irvine, California 92618

Dear Mr. Mercer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed an advertisement for Interpore Cross International's (Interpore) BonePlast™ (formerly Osteoplast Bone Void Filler). The advertisement was placed in the January/February 2000 edition of the Journal of the American Academy of Orthopedic Surgeons. BonePlast™ is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act.

The Osteoplast Bone Void Filler designated, K991854 is indicated "only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Osteoplast Pellets are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The Pellets provide a bone void filler that resorbs and is replaced with bone during the healing process. Because the Pellets are biodegradable and biocompatible, [they] may be used at an infected site."

Although Interpore did not receive clearance that BonePlast™ could be injected directly into a bony void or gap, we believe that your advertisement has made such representations. The advertisement titled "The Future Of Bone Grafting Is Now Taking Shape" pictorially represents BonePlast™ material being extruded through a syringe into voids that were used to spell the name of the product. This representation and the caption "Injectable, Moldable, Versatile – BonePlast™ is a representation that practitioners may inject Boneplast from its liquid or paste state directly into a bony void or gap. The text of the advertisement makes similar representations, "After mixing, BonePlast can be aspirated into a syringe and extruded, or it can be hand-molded to the desired shape... We invite you to learn how the versatility of this injectable, moldable bone void filler can benefit your patients."

These statements and other representations are contrary to the instructions for use, which require that BonePlast™ be in its hardened state prior to being placed in the bony void. This may be accomplished using the cleared molds or by manual molding. The agency does not support any representation that BonePlast™ when applied directly to a bony

void as a paste is safe or effective. The agency, in fact, has expressed serious concerns that factors associated with the hardening of BonePlast™ or similar materials in bony voids or gaps are unknown.

Another portion of the text of your advertisement also contains the following statement, “[a]dditional reported applications include usage with antibiotics, growth factors, and various therapeutic drugs.*” BonePlast™ has not been approved to be used with antibiotics, growth factors, or any therapeutic drugs and your reference to reports in the literature and your offer to provide such literature are inappropriate and result in the promotion of an unapproved application. Interpore may only provide such reprints in response to an unsolicited request and your solicitation in this advertisement will now make it difficult to fill requests for these reprints.

Claims that imply that BonePlast™ can be used as an injectable material directly at the site of the defect as well as claims that imply that BonePlast™ can be used with growth factors, antibiotics, and therapeutic drugs have misbranded and adulterated the device within the meanings of sections 502(o) and 501 (f)(1)(B) of the Act. The BonePlast™ material is misbranded because a notice or other information respecting the device was not provided to the FDA as required by section 510(k) and it has not been found to be substantially equivalent to a predicate device for the uses claimed. The device is adulterated because it is a class III device under section 513(f) and does not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for investigational device exemptions under section 520(g).

FDA’s regulations at 21 CFR 801.4 provide that the term “intended uses” of a device refers to the objective intent of the persons legally responsible for the labeling of a device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims that your device can be injected directly at the site of the defect as well as claims that your device can be used with growth factors, antibiotics, and therapeutic drugs changes the intended use for which BonePlast™ was cleared. Pursuant to section 510(k) of the Act and as provided in 21 CFR 807.81(a)(3)(ii), claims that constitute a major change in the cleared intended use of a device require the submission of premarket notification to FDA.

The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunctions and/or civil penalties. This letter is not intended to be an all-inclusive list of deficiencies associated with BonePlast™.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address any misleading information currently in the marketplace and actions to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Terri Garvin, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office (HFR-PA-200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

A handwritten signature in black ink, appearing to read "Lillian Gill", written over the printed name and title.

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health